

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

A8130.0153/P153

| | |
|---|-----------------------------|
| Application Number 10/660,601-Conf. #7642 | Filed September 12, 2003 |
|---|-----------------------------|

| |
|--|
| First Named Inventor R. D. Grafton et al. |
|--|

| | |
|------------------|---------------------------|
| Art Unit 3773 | Examiner M. K. Ryckman |
|------------------|---------------------------|

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

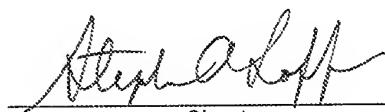
This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

applicant /inventor.
 assignee of record of the entire interest.
 See 37 CFR 3.71. Statement under 37 CFR 3.73(b)
 is enclosed. (Form PTO/SB/96)



Signature

 Stephen A. Soffen
 Typed or printed name

attorney or agent of record.

Registration number 31,063

(202) 420-4879

Telephone number

attorney or agent acting under 37 CFR 1.34.

Registration number if acting under 37 CFR 1.34. _____

July 19, 2010

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
 Submit multiple forms if more than one signature is required, see below*.



*Total of 1 forms are submitted.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
R. D. Grafton et al.

Application No.: 10/660,601

Confirmation No.: 7642

Filed: September 12, 2003

Art Unit: 3773

For: FULLY-THREADED SUTURE ANCHOR
WITH INSERT-MOLDED SUTURE

Examiner: M. K. Ryckman

PRE-APPEAL BRIEF REQUEST FOR REVIEW

MS AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Madame:

In the final Office Action dated February 17, 2010, claims 1-6, 8, 11-13, 16 and 19 were rejected under 35 U.S.C. §103(a) as being unpatentable over Grafton et al. (U.S. Patent No. 5,964,783) ("Grafton") in view of Greenfield (U.S. Patent No. 5,584,835). This rejection is respectfully traversed for at least two reasons: (i) the cited prior art references do not teach or suggest all limitations of claims 1-6, 8, 11-13, 16 and 19; and (ii) there is no motivation to combine the cited prior art references.

**THE CITED PRIOR ART REFERENCES DO NOT DISCLOSE OR
SUGGEST ALL LIMITATIONS OF THE CLAIMED INVENTION**

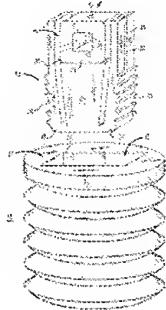
Grafton and Greenfield, considered alone or in combination, do not disclose or suggest all limitations of claims 1, 5 and 11. Grafton specifically teaches against the claimed invention and, thus, Grafton cannot disclose or suggest all limitations of the claimed invention. In the "Background of the Invention" section of the present application, the inventors describe Grafton in ¶[0005] as follows:

U.S. Pat. No. 5,964,783 to Grafton et al. . . . discloses a threaded bioabsorbable suture anchor provided with a loop of suture that is insert-molded directly into the suture anchor during manufacturing. The proximal end of the suture anchor body of the '783 patent is provided with a non-threaded hexagonal drive head. The insert-molded suture preferably extends through the entire length of the suture anchor body and exits through the drive head at the proximal end of the anchor to form a loop of suture external to the suture anchor. In this manner, the suture forming the loop is secured effectively to the threaded suture anchor and is prevented from becoming detached from the anchor. However, because the suture anchor of '783 patent is provided with the non-threaded hexagonal head, the threads of the threaded anchor body do not reach the top of the cortical bone when the suture anchor is installed. Thus, the threaded anchor body tends to move up to the bone surface by at least a distance equal to the length of the non-threaded hexagonal head, such that the drive head may become proud to the surface. Moreover, the suture of the eyelet, which is disposed outside the suture anchor in back of the drive head, may abrade the adjacent tissue.

To overcome the disadvantages of Grafton, the inventors state in the specification that a “need exists for a bioabsorbable suture anchor having a suture loop that does not extend beyond the drive head and does not abrade tissue” ([0006]) proposing, instead (as the invention), an anchor with a suture eyelet (suture loop) disposed completely within the anchor body. This allows the suture anchor body to be “fully threaded”, providing improved fixation. For at least these reasons, explained more fully below, Grafton cannot and does not disclose or suggest all limitations of the claimed invention, and one skilled in the art would not have been motivated to consider Grafton (much less to combine Grafton with other prior art references) to arrive at the claimed invention.

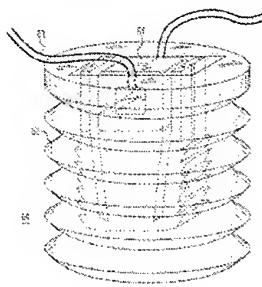
Specifically, Grafton does not disclose or suggest “a suture eyelet . . . disposed completely within the anchor body,” or a “suture loop disposed completely within the drive socket,” as claims 1, 5 and 11 recite. Loop 11 of Grafton '783 (which would arguably correspond to the “suture eyelet” or “suture loop” of the claimed invention) is located outside the hexagonal drive head 10 and outside the body 4, and not “completely within the anchor body,” as in the claimed invention.

Greenfield fails to address the deficiencies of Grafton. Greenfield is silent about a “suture eyelet” or “suture loop” provided “completely within the anchor body,” as in the claimed invention. Greenfield teaches a two-part device for suturing soft tissue to bone and none of the limitations of the claimed invention.



In the Office Action dated February 17, 2010, the examiner asserts that “Greenfield teaches the suture eyelet being disposed completely within the anchor body” (Office Action at 4). Applicants disagree. Figure 5 of Greenfield (reproduced below) does not illustrate an eyelet of a suture strand that is *insert-molded* within the anchor body.

FIG. 5



As detailed by Greenfield (and as shown in Figure 5 above), Greenfield simply teaches “sutures 63 . . . held by friction” when suture anchor 61 fully engages bone anchor 62 (col. 9, ll. 40-44). Greenfield does not disclose or suggest, however, a bioabsorbable suture anchor with a suture strand that is insert-molded into the bioabsorbable in the form of an eyelet disposed completely within the bioabsorbable anchor body. Even if *arguendo* Greenfield would disclose an eyelet within

the body of an anchor, Greenfield still does not disclose or suggest “a suture eyelet formed *of a strand of a first suture insert-molded into the bioabsorbable anchor body*,” as in the claimed invention (emph. added). Suture 63 of Greenfield is not provided within the body of the anchor, it is not insert-molded, and Greenfield simply does not relate in any way to the present invention.

NO MOTIVATION TO COMBINE THE REFERENCES EXISTS

A person skilled in the art would also not have been motivated to combine Grafton with Greenfield for at least the following four reasons: First, Grafton teaches against the claimed invention and, thus, there is no motivation for one skilled in the art to consider Grafton (or to combine Grafton with any other reference) to arrive at the claimed invention.

Second, one skilled in the art would not have been motivated to combine the single piece, insert-molded suture anchor of Grafton (provided with a suture loop which extends outside the body anchor) with Greenfield (which teaches two separate structures – a suture anchor 11 and a bone anchor 12 – that are designed to lock into each other). There is simply no connection between these two disparate references and it would be illogical indeed for one skilled in the art to modify the protruding eyelet of Grafton with the friction-held suture of Greenfield, to address a problem that does not even exist in Grafton.

Third, the Examiner’s reliance upon the teachings of the instant application to provide motivation to modify the teachings of the cited prior art reference to arrive at the claimed invention is inadmissible. It is improper to use Applicant’s own disclosure as a roadmap for modifying references. “The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and *not based on applicant’s disclosure*.[”] *In re Vaeck*, 947 F.2d 488, (Fed. Cir. 1991); MPEP § 706.02(j) (emphasis added). “The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done.” MPEP § 706.02(j). “To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner *must present a convincing line of reasoning* as to why the artisan would

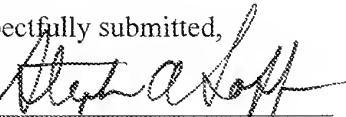
have found the claimed invention to have been obvious in light of the teachings of the references.”
Id. (quoting *Ex parte Clapp*, 227 USPQ 972, 973 (B.P.A.I. 1985) (emphasis added).

In the present case, Grafton and Greenfield do not expressly or impliedly suggest the claimed invention, and the Examiner has failed to present a clear and convincing line of reasoning regarding the obviousness of the claimed invention in view of the cited prior art references. There is simply no motivation to combine the two-part device of Greenfield (with a first part sutured to soft tissue and a second part embedded in a bone, the first and second parts being mechanically coupled in a reversible engagement) with the single-piece anchor of Grafton, to form an insert-molded suture anchor with a recessed eyelet (especially when Grafton teaches against the claimed invention).

Fourth, any combination of the two-part elements of Greenfield with the single part, insert-molded suture anchor of Grafton would require a substantial reconstruction and redesign of the elements of Grafton (“[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.” M.P.E.P. § 2143.01 (citing *In re Ratti*, 270 F.2d 810 (CCPA 1959)). In the present case, the proposed combination would require an eyelet within the body of the anchor of Grafton but with the suture strands extending outside the body of the anchor (as taught by Greenfield) and, thus, elimination of the insert-molding process of Grafton (i.e., a complete reconstruction and redesign of the insert-molded suture anchor of Grafton).

Dated: July 19, 2010

Respectfully submitted,

By 
Stephen A. Soffen

Registration No.: 31,063
DICKSTEIN SHAPIRO LLP
1825 Eye Street, NW
Washington, DC 20006-5403
(202) 420-2200
Attorneys for Applicants